In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-845V
Filed: August 15, 2024

ANNETTE MOLINA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for petitioner.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On July 13, 2020, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered a right shoulder injury resulting from her October 4, 2018 influenza ("flu") vaccination. (ECF No. 1.) For the reasons discussed below, I now find that petitioner is *not* entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. § 300aa-11(c).

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A)-(B); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a).

The Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of vaccine administration. § 300aa-14(a), *amended by* 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *see also Pafford ex rel. Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury" in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting ex rel. Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 872-73 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B).

II. Procedural History

Based on the allegations in the petition, this case was initially assigned to the Chief Special Master as part of the Special Processing Unit ("SPU"). (ECF No. 9-10.) Petitioner filed an affidavit and medical records marked as Exhibits P1-P11. (ECF Nos. 6, 14, 17, 19.) Petitioner then filed a motion for a ruling on the record and respondent filed a combined motion response and Rule 4(c) Report. (ECF Nos. 25, 28.) Once briefing was complete, the Chief Special Master filed his Findings of Fact and Conclusions of Law. (ECF No. 32.) The Chief Special Master dismissed petitioner's Table SIRVA claim but indicated that petitioner should have an opportunity to prove that "her generalized SIRVA-like injury" was caused-in-fact by her vaccination. (*Id*. at 9.) The case was reassigned to the undersigned for that purpose on September 14, 2022. (ECF Nos. 33-34.)

Petitioner then filed an expert report by physical medicine and rehabilitation specialist Naveed Natanzi, D.O., with supporting materials. (ECF Nos. 37-39; Exs. P12-

P14.) Respondent responded with a report by orthopedic surgeon Geoffrey Abrams, M.D., accompanied by supporting materials. (ECF No. 42; Exs. A-B.) Petitioner subsequently filed a supplemental report by Dr. Natanzi (Ex. P15) and additional medical records (Exs. P16-P18). (ECF Nos. 46, 48.) Respondent opted not to file a further expert report. (ECF No. 47.) Thereafter, petitioner filed another motion for a ruling on the record. (ECF No. 49.) Respondent filed a response and petitioner filed a reply. (ECF Nos. 51-52.)

In light of the above I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck ex rel. C.J.K. v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

Petitioner received the vaccination at issue in her right deltoid on October 4, 2018. (Ex. P1, p. 3.) She was 28 years old at the time and had a prior history of lumbar disc herniation and chronic back pain from an automobile accident in 2015. (Ex. P4, p. 10.) For the reasons discussed in the prior ruling, the Chief Special Master accepted petitioner's written statement and medical records as preponderately supporting an "immediate" onset of shoulder pain after the vaccination. (ECF No. 32, pp. 7-8.)

About four months later, petitioner was seen by occupational health on February 6, 2019, for complaints of post-vaccination right arm pain. (Ex. P4, pp. 162-63.) Petitioner described pain in the right deltoid that began post-vaccination and increased since December. (*Id.* at 162.) She indicated that she could not raise her arm beyond 90 degrees of flexion and that the pain radiated from the deltoid to the upper back and across to the opposite shoulder. (*Id*.) However, on physical examination she had no tenderness to palpation and full range of motion of the right shoulder. (*Id*. at 163.) For this and for other complaints, she was directed to follow up with a primary care provider. (*Id*.)

Petitioner presented to a primary care provider on March 19, 2019. (Ex. P5, p. 26.) On physical examination, petitioner had tenderness over the deltoid and acromioclavicular joint. (*Id.* at 28.) She had full passive range of motion, but pain with elevation above 90 degrees and with internal and external rotation. (*Id.*) She had some crepitus and active range of motion was limited to 110 degrees of elevation. (*Id*.) She was initially assessed as having a disorder of the bursa and tendons in the right shoulder region, but calcific tendinitis was more specifically assessed after x-rays showed "tiny calcification adjacent to the greater tuberosity." (*Id*. at 29.) She was referred to a physiatrist and physical therapy. (*Id.*) She was also prescribed

diclofenac.[3] (*Id*.) However, petitioner did not initially complete any physical therapy or see the physiatrist. (Ex. P5, p. 13.)

On July 17, 2019, petitioner followed up with her primary care provider regarding her shoulder pain. (Ex. P5, p. 13.) She reportedly had been using diclofenac "off-and-on with limited relief." (*Id.*) A repeat x-ray showed enlargement of the calcification seen on the prior x-ray; however, symptoms were reportedly neither worse nor resolved. (*Id*. at 13-14, 41.) The impression remained the same and petitioner was again referred to physical therapy and physiatry. (*Id.* at 16.) She was prescribed meloxicam.[4] (*Id*.)

Petitioner presented to a physiatrist for the first time on August 26, 2019. (Ex. P7, pp. 19-25.) On physical examination, petitioner did not have pain on palpation over the right later shoulder. (*Id.* at 22.) She had full strength. (*Id.*) She had reduced flexion and abduction of the right shoulder (90 degrees/nl 180 degrees) and a 50% reduction in internal rotation. (*Id*.) Empty can test[5] and Hawkins test[6] were positive. (*Id*.) She was diagnosed with calcific tendinitis. (*Id*. at 24.) Regarding vaccine causation, the physiatrist wrote:

> She expresses concerns of SIRVA which is well documented in the literature. Typically injury to the shoulder after an injection likely occurs with an injection into the joint capsule as opposed to the deltoid muscle. She describes her pain [as] at the site of the injection which brings her concern. The area of her discomfort is in the lower aspect of the deltoid muscle. This is likely referred pain from calcific tendinitis, but it is difficult to say whether

[3] "Diclofenac" is "a nonsteroidal anti-inflammatory drug." *Diclofenac,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=13937&searchterm=diclofenac (last visited Aug. 12, 2024).

[4] "Meloxicam" is "a nonsteroidal anti-inflammatory drug used in the treatment of osteoarthritis." *Meloxicam,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=30286&searchterm=meloxicam (last visited Aug. 13, 2024).

[5] An "empty can test" or "Jobe's test" is "used to diagnose shoulder injuries," and "examine the integrity of the supraspinatus muscle and tendon." *Empty can/Full can tests,* WIKIPEDIA, https://en.wikipedia.org/wiki/Empty_can/Full_can_tests (last visited Aug. 12, 2024). During the test, "the arm is rotated to full internal rotation (thumb down)." (*Id.*) "A positive test result suggests a tear to the supraspinatus tendon or muscle, or neuropathy of the suprascapular nerve." (*Id.*)

[6] The "Hawkins-Kennedy Test" is used to evaluate a shoulder injury. *Hawkins-Kennedy test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Hawkins%E2%80%93Kennedy_test (last visited Aug. 12, 2024). A positive test is "likely indicative of damage of the tendon of the supraspinatus muscle." (*Id.*) During the test, the patient sits "with their shoulder flexed to 90 [degrees] and their elbow flexed to 90 [degrees]. The examiner grasps and supports proximal to both, the patient's wrist and elbow, to ensure maximal relaxation, then quickly rotates the patient's arm internally." (*Id.*) Pain below the acromioclavicular joint is a positive test result. (*Id.*)

> this actually occurred from an inappropriate injection which would have been higher.

(*Id*.) Physical therapy was again recommended. (*Id*.)

Over a year later, petitioner presented to an orthopedist on September 28, 2020. (Ex. P11, p. 7-8.) Petitioner has an extensive medical history in the interim; however, it is not illuminating with respect to the correct diagnosis of her right shoulder condition or its potential connection to her vaccination. On physical exam, the orthopedist found impingement on Hakwins and Neer[7] testing as well as a positive O'Brien's test.[8] (*Id.* at 7.) However, the empty can test was negative. (*Id*.) The orthopedist maintained the diagnosis of calcific tendinitis, though he felt the chronicity of her pain was atypical. (*Id*. at 8.) Petitioner's x-ray showed a small post superior calcification, though the calcification was not well visualized on MRI. (*Id*.; Ex. P17, p. 543.) The MRI concluded "[f]indings suggestive of mild supraspinatus tendinitis" and "[s]mall subchondral cysts in the humeral head." (Ex. P17, p. 543.) The subscapularis and infraspinatus tendons were noted to be unremarkable. (*Id*.) A therapeutic injection into the subacromial space was completed and a possible subacromial decompression and resection of the calcium deposit was noted as a potential further course of action. (Ex. P11, p. 8.) Petitioner returned to the orthopedist about four months later on February 1, 2021. (*Id*. at 4-6.) She reported having experienced temporary relief from the therapeutic injection; however, petitioner's condition was reportedly "getting slowly worse," though the pain was noted to be "mild." (*Id*. at 6.) Petitioner disfavored surgery and no further action was taken. (*Id.*) Her diagnosis remained unchanged. (*Id*.)

The remainder of petitioner's medical records do not appear to be informative of the issues presented by the parties.

IV. Expert Reports

a. Naveed Natanzi, D.O.[9]

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[7] The "Neer impingement test" is "designed to reproduce symptoms of rotator cuff impingement through flexing the shoulder and pressure application." *Near impingement test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Neer_impingement_test (last visited Aug. 13, 2024).

[8] The "O'Brien's Test" "indicate[s] potential labral . . . or acromioclavicular lesions." *O'Briens Test,* PHYSIOPEDIA, https://www.physio-pedia.com/O%27Briens_Test (last visited Aug. 13, 2024). During the test, the patient sits and the arm is "placed in 90 degrees of shoulder flexion and 10-15 degrees of horizontal adduction." (*Id.*) "Depth of symptoms must also be assessed as superficial pain can indicate acromioclavicular joint symptoms and deep pain is more often a sign of a labral lesion." (*Id.*)

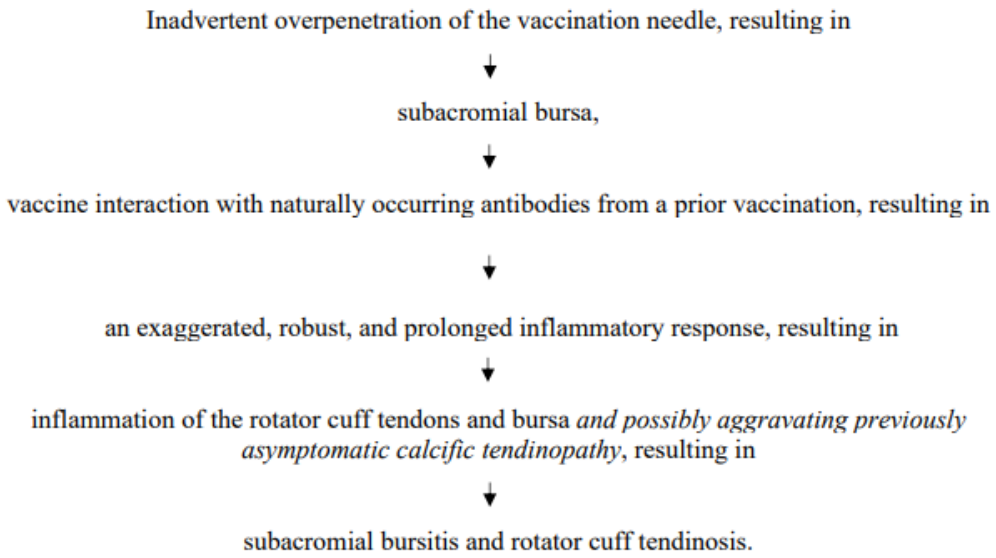
[9] Dr. Naveed Natanzi received his bachelor's degree from the University of California at Santa Barbara and his Doctor of Osteopathy from Western University of Health Sciences. (Ex. 13, p. 2.) He completed a traditional rotating internship at Downey Regional Medical Center, a residency in physician medicine and rehabilitation at the University of California, Irving, and a fellowship in interventional regenerative sports and spine medicine at Bodor Clinic. (*Id.* at 1-2.) He is board certified in physical medicine and rehabilitation, and pain management. (*Id.* at 1.) He currently works at Regenerative Sports and Spine

According to Dr. Natanzi, petitioner's clinical history is consistent with a SIRVA-like injury because she had no prior history of shoulder pain, onset of shoulder pain within 48 hours of vaccination, and documented reduction in her range of motion as of February 6, 2019.[10] (Ex. P12, p. 6 (citing Ex. P3, p. 6).) Furthermore, petitioner's positive response to a subacromial injection on September 28, 2020 is suggestive of an inflammatory process such as bursitis or a rotator cuff injury. (*Id*. (citing Ex. P11, p. 7).) All of this strongly suggests a causal relationship to petitioner's vaccination. (*Id*.) In particular, he cites four records – by Physician's Assistant ("PA") Gibson on March 19, 2019 (Ex. P5, p. 26); by PA Chappell on August 26, 2019 (Ex. P5, p. 49); and by Dr. Epstein on September 28, 2020 and February 1, 2021 (Ex. P11, pp. 4, 7) – that document restriction in flexion and abduction, which are planes respondent's expert agrees are "universally accepted directions for loss of motion in SIRVA cases." (Ex. P15, p. 2.)

Dr. Natanzi cites eighteen different publications, mostly case reports, addressing various types of shoulder conditions coming to medical attention post-vaccination. (Ex. P12, pp. 3-5.) He also cites a study by Trollmo, et al., in which it was demonstrated that intraarticular injection of the flu vaccine results in a stronger immune response compared to subcutaneous injection. (*Id*. at 3 (citing C. Trollmo et al., *Intra-Articular Immunization Induces Strong Systemic Immune Response in Humans,* 82 CLINICAL & EXPERIMENTAL IMMUNOLOGY 384 (1990) (Ex. P14, Tab i)).) Dr. Natanzi explains his theory via the following flowchart:

Institute, as a staff physician at VA Long Beach Healthcare System, and a medical director at Tova Surgical Center. (*Id.*) He has also submitted eight publications. (*Id.* at 3.)

[10] In fact, although petitioner reported reduced range of motion to occupational health in February of 2019, reduced range of motion was not confirmed by physical exam until she presented to her primary care physician on March 19, 2019. (*Compare* Ex. 4, p. 162-63 *and* Ex. 5, p. 26-29.) However, given the limitations of the occupational health record, I find the physical therapist's documented physical exam to be more reliable.



(*Id*. at 7.)

Dr. Natanzi acknowledges that petitioner had calcific tendinitis[11] but opines that it was an incidental finding that played no role in petitioner's perception of shoulder pain. (Ex. P12, p. 6.) He notes that between 2-20% of calcific tendinitis is asymptomatic. (*Id*. (citing Min-Su Kim et al., *Diagnosis and Treatment of Calcific Tendinitis of the Shoulder,* 23 CLINICS SHOULDER & ELBOW 210 (2020) (Ex. P14, Tab t)).) Nonetheless, he also cites a case report by Klabklay, et al., that hypothesized that a vaccine-mediated reaction resulted in a previously asymptomatic calcific tendonitis becoming symptomatic. (*Id*. at 7 (citing Prapakorn Klabklay et al., *A COVID-19 Vaccination Precipitating Symptomatic Calcific Tendinitis: A Case Report,* 74 ANNALS MED. & SURGERY 103347 (2022) (Ex. P14, Tab u)).)

In his supplemental report, Dr. Natanzi explained that calcific tendinitis and SIRVA can have similar presentations and that context is what differentiates between the different pathologies. (Ex. P15, p. 1.) Thus, Dr. Natanzi reiterates the emphasis he places on the fact that petitioner's pain arose for the first time within 48 hours of vaccination, which he opines is incompatible with the weeks to months long onset of calcific tendinitis. (*Id*. at 1-2.) But for this factor, Dr. Natanzi indicates he would otherwise likely offer an opinion "more in line with those of Dr. Abrams." (*Id*. at 2.) However, whereas Dr. Abrams highlights exam findings of full range of motion, Dr. Natanzi does stress other exam findings where reduced range of motion is noted. (*Id*. at 2 (citing Ex. P5, p. 26 (March 19, 2019 exam with PA Gibson); Ex. P5, p. 49 (August

[11] Throughout his reports, Dr. Natanzi refers to the condition at issue as calcific tendinopathy. However, Dr. Abrams refers to the same condition as calcific tendinitis. Based on my review of the record, Dr. Abrams's word choice is more consistent with the literature. Accordingly, this decision will use the term calcific tendinitis, except where directly quoting Dr. Natanzi. I do not understand Dr. Natanzi to be invoking any significant distinction by using the term tendinopathy.

26, 2019 exam with PA Chappell); Ex. P11, pp. 4, 7 (September 28, 2020 and February 1, 2021 exams with Dr. Epstein).)

b. Geoffrey Abrams, M.D.[12]

Based on his assessment of the medical records, where he notably doubts the timing of onset as found by the Chief Special Master, Dr. Abrams opines that petitioner's shoulder pain is most likely explained by her confirmed calcific tendonitis rather than by SIRVA. (Ex. A, p. 8.) He notes the diagnosis is demographically appropriate for petitioner, as it typically affects the young and is more often seen in women. (*Id*. at 6 (citing Cathy A. Speed & Brian L. Hazleman, *Calcific Tendinitis of the Shoulder,* 340 NEW ENG. J. MED. 1582 (1999) (Ex. A, Tab 3)).) Dr. Abrams also explains that calcific tendinitis is one of the most frequent causes of shoulder pain, occurring in up to 42% of symptomatic shoulders. (*Id*. (citing Christelle Darrieutort-Laffite et al., *Calcific Tendonitis of the Rotator Cuff: From Formation to Resorption,* 85 JOINT BONE SPINE 687 (2018) (Ex. A, Tab 1)).) By contrast, it appears incidentally only 2.7% of the time. (*Id*. (citing Harrison L. McLaughlin, *Lesions of the Musculotendinous Cuff of the Shoulder: III. Observations on the Pathology, Course and Treatment of Calcific Deposits,* 124 ANNALS SURGERY 354 (1946) (Ex. A, Tab 2)).) Therefore, he disagrees that it would be likely to have been an incidental finding for petitioner.

Even setting aside Dr. Abrams's disagreement as to the timing of onset, he opines that petitioner's condition is inconsistent with SIRVA because her exam findings do not match what is expected in SIRVA in terms of limited range of motion. (Ex. A, p. 7.) According to Dr. Abrams, whereas loss of external rotation, forward elevation, and abduction are expected in SIRVA, petitioner had documented full range of motion from the point of her first medical encounter through July 2019. (*Id*. at 7-8 (citing Ex. P3, p. 3 (February 6, 2019); Ex. P5, p. 26 (March 19, 2019); Ex. P5, p. 19 (July 17, 2019).)

Calcific tendinitis has a natural course that includes an acute phase associated with severe pain. (Ex. A, p. 6.) That phase results in diffusion of calcium crystals into the bursa, leading to inflammation that in turn causes pain and restriction in movement. (*Id*. (citing Darrieutort-Laffite et al., *supra,* at Ex. A, Tab 1; McLaughlin, *supra,* at Ex. A, Tab 2; Speed & Hazleman, *supra,* at Ex. A, Tab 3).) As Dr. Abrams explains it, this is a distinct, or alternative, etiology from SIRVA. (*Id*.) Dr. Abrams is not persuaded by the Klabklay, et al., case report cited by Dr. Natanzi, because that report involved a single patient experiencing calcific tendinitis of the subscapularis tendon, which is less relevant in a proposed SIRVA. (*Id*.)

[12] Dr. Geoffrey Abrams received his bachelor's degree from Stanford University and his Medical Degree from the University of California, San Diego. (Ex. B, p. 1.) He completed a surgical internship in the Department of General Surgery and a residency in the Department of Orthopedic Surgery at Stanford University. (*Id.*) He also completed a fellowship in orthopedic sports medicine at Rush University Medical Center. (*Id.*) He is board certified in orthopedic surgery and has a subspecialty certificate in orthopedic sports medicine. (*Id.* at 2.) He has authored 67 peer reviewed publications, five commentaries, 84 peer reviewed abstracts, and 26 book chapters. (*Id.* 2-8; 10-21.)

V. Party Contentions

In her motion, petitioner acknowledges that her Table SIRVA claim was previously dismissed and argues that she has otherwise presented a cause-in-fact claim pursuant to the *Althen* test. (ECF No. 49, p. 19.) Petitioner asserts that she has met her burden of proof under *Althen* prong one via the commonly understood mechanism of injury underlying the SIRVA concept, namely that post-vaccination inflammation of the bursa can activate pathology otherwise affecting other structures of the shoulder. (*Id*. at 20-23.) She does not specifically address Dr. Natanzi's opinion that calcific tendinitis in particular can be activated by this process, reserving discussion of calcific tendinitis to alternative causation. (*See id*. at 23.) Petitioner argues that relative to her assertion of a SIRVA-like injury under *Althen* prong one, the Chief Special Master's prior ruling as to a 48-hour onset already confirms that she satisfies the timing requirement under *Althen* prong three. (*Id*. at 26.)

Regarding *Althen* prong two, petitioner argues that the vaccination did cause her injury based on her assertions that (1) onset is appropriate to infer vaccine causation, (2) findings of calcific tendinitis were merely incidental, (3) documented restricted motion, tenderness at the deltoid, and impingement signs are indicative of SIRVA, (4) she had no prior history of shoulder dysfunction, and (5) her response to steroid treatment indicates an inflammatory process. (ECF No. 49, pp. 27-29.) Regarding an alternative cause, petitioner argues that respondent's assertion that petitioner suffered calcific tendinitis is flawed for two reasons. First, petitioner asserts "it is medically impossible for Petitioner's shoulder pain to occur within 48 hours of the flu vaccine but be caused by a spontaneous and once-asymptomatic calcific tendinitis." (*Id*. at 31.) Second, Dr. Abrams is incorrect to assert that petitioner did not have reduced range of motion. (*Id*.)

In response, respondent first seeks to reargue the Chief Special Master's finding as to onset. (ECF No. 51, pp. 13-17.) Turing to causation in fact, respondent argues that petitioner cannot merely rely on the broader "SIRVA" concept in a cause-in-fact case without identifying a more particularized shoulder injury. (*Id.* at 17-20.) Regarding the shoulder injury diagnosed by the treating physicians, he contends that Dr. Natanzi's extension of SIRVA under *Althen* prong one to include calcific tendinitis is speculation, supported only by a single case report. (*Id*. at 23-24.) He contends that "[a]t base there really is not even a theory here, but rather a basic assertion that petitioner suffered from vaccine-related inflammation *somehow* because of her calcific tendinitis." (*Id*. at 24 (emphasis original).) Under *Althen* prong two, respondent argues that the calcific tendinitis diagnosed by the treating physicians is the cause of petitioner's condition and cannot be dismissed as an incidental finding. (*Id*. at 25-27.) Contrary to petitioner's assertion of impossibility, respondent stresses that calcific tendinitis does include an acute phase. (*Id*. at 27.)

In reply, petitioner argues that she can pursue a cause-in-fact SIRVA claim because it is a medically recognized injury with a distinct pathology. (ECF No. 52, p. 4.)

VI. Analysis

a. Table Injury and Prior Findings of Fact

I have considered the parties' arguments and the expert reports filed after the Chief Special Master issued his prior ruling; however, I do not see any reason to reopen the Chief Special Master's dismissal of petitioner's Table Injury claim or any of the factual findings within that ruling. Generally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred. *See McGowan v. Sec'y of Health & Human Servs.,* 31 Fed. Cl. 734, 737–38 (1994). In most cases, however, a judicial officer such as a special master departs from previously decided issues only in the event of "new evidence, supervening law, or a clearly erroneous decision." *Id.* at 737; *see also Sullivan v. Sec'y of Health & Human Servs.,* No. 10–398V, 2015 WL 1404957, at *20 n.36 (Fed. Cl. Spec. Mstr. Feb. 13, 2015).

Dr. Natanzi's explanation that calcific tendinitis can sometimes be an asymptomatic, incidental finding does not overcome the Chief Special Master's conclusion that the presence of calcific tendonitis in this particular case defeats a Table SIRVA claim under QAI criterion four. (ECF No. 32, p. 9.) I have previously observed that, when respondent asserts that shoulder pathology defeats a SIRVA under prong four, "the question raised by respondent's argument is whether petitioner's own clinical history indicates that her shoulder pathology wholly explains her symptoms independent of vaccination." *Lang v. Sec'y of Health & Human Servs*., No. 17-995V, 2020 WL 7873272, at *13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020). Here, the Chief Special Master specifically explained that the treating physicians addressed whether a SIRVA-like process could be distinguished from her otherwise diagnosed calcific tendonitis and were unable to do so. (ECF No. 32, p. 9.) For the reasons discussed below, there is a debate between the experts as to whether post-vaccination inflammation may intersect with petitioner's calcific tendinitis to explain her overall presentation; however, that is a theory that requires adjudication under the *Althen* test. As Dr. Abrams explains, calcific tendinitis is a condition that can in itself present with acute onset of shoulder pain. (Ex. A, p. 6.) Accordingly, as the Chief Special Master held, the treating physicians' diagnosis of calcific tendinitis unrelated to vaccination is sufficient to remove this case from the Table injury context even without being entirely dispositive of a cause-in-fact claim. *Accord Durham v. Sec'y of Health & Human Servs*., No. 17-1899V, 2023 WL 3196229, at *15 (Fed. Cl. Spec. Mstr. May 2, 2023) (explaining that "[i]n the cause-in-fact context, petitioner's claim can be more appropriately assessed based on an affirmative showing of a logical sequence of cause and effect between her vaccination and a shoulder pathology, balanced against the confounding signs and symptoms, rather than on the process-of-elimination type showing inherent to a Table SIRVA.") ; *see also Lindsay v. Sec'y of Health & Human Servs.*, No. 20-1650V, 2023 WL 4858539, at *9 (Fed. Cl. Spec. Mstr. June 29, 2023) (dismissing Table SIRVA claim due to calcific tendinitis but permitting cause-in-fact claim to proceed even though "doubtful"); *see also Smith v. Sec'y of Health & Human Servs*., 20-300V, 2023 WL 6620362 (Fed. Cl. Spec. Mstr. Feb. 24, 2023) (dismissing Table claim only due to calcific tendinitis).

Dr. Abrams's interpretation of the medical records regarding onset likewise does not disturb the Chief Special Master's finding that onset of petitioner's shoulder pain did occur within 48 hours of vaccination. While petitioner did delay seeking treatment, the Chief Special Master explained why the medical records and petitioner's written statements collectively establish that onset of her shoulder pain more likely than not occurred within 48 hours of vaccination. (ECF No. 32, pp. 7-8.) Dr. Abrams believes, in effect, that because he opines petitioner had calcific tendinitis, the medical records should be interpreted in the manner most consistent with the more typical onset of calcific tendonitis. (Ex. A, pp. 6-7.) However, the diagnosis does not call the Chief Special Master's weighing of the medical records into question or itself resolve the factual issue. The treating physicians diagnosed calcific tendinitis while also recording that petitioner's shoulder pain arose acutely after vaccination. In that regard, Dr. Abrams himself asserts that calcific tendinitis can result in result in acute onset of shoulder pain. (*Id.* at 6.)

Accordingly, upon consideration of the record as a whole, I adopt the Chief Special Master's findings of fact and dismissal of petitioner's Table SIRVA claim in full and for the reasons stated therein. (*See* ECF No. 32.)

b. *Althen* prong one

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford,* 451 F.3d at 1355-56. Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Boatmon ex rel. J.B. v. Sec'y of Health & Human Servs.,* 941 F.3d 1351, 1359 (quoting *Knudsen*, 35 F.3d at 548-49).

The theory underlying SIRVA and SIRVA-like injuries is well known in the program and well-illustrated by the flow chart included in Dr. Natanzi's report. (Ex. P12, pp. 7.) In short, injection of a vaccination may affect the subacromial bursa, resulting in inflammation of the shoulder capsule itself. In some cases, this may lead directly to painful bursitis. In other cases, the inflammatory process affecting the shoulder capsule may activate previously-asymptomatic shoulder joint dysfunction, such as rotator cuff tears or adhesive capsulitis. (S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA),* 28 VACCINE 8049, 8051 (2010) (Ex. P14, Tab b, p. 3); Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction,* 25 VACCINE 585 (2007) (Ex. P14, Tab g).). Indeed, Dr. Abrams has not challenged this general concept.

Thus, to the extent petitioner asserts that her calcific tendinitis was merely incidental and her shoulder pain is explained by a SIRVA-like injury, she is persuasive in contending that the evidence of record preponderantly supports a theory of causation for such an injury. *See Morris v. Sec'y of Health & Human Servs*., No. 19-1570V, 2023 WL 5092691, at *6 (Fed. Cl. Spec. Mstr. July 11, 2023) (explaining of the Atanasoff and Bodor publications that "[r]egardless of respondent's argument that the broader SIRVA concept is a create of his own rulemaking, respondent cannot reasonably argue that these studies which he had already himself specifically endorsed are not persuasive as support for a medical theory of causation.")

However, in the interest of completeness, I must also address the additional theoretical question raised by Dr. Natanzi's report. If petitioner's calcific tendinitis is not merely incidental, then Dr. Natanzi further asserts that calcific tendinitis in particular can be among the conditions aggravated by inflammation of the subacromial bursa. (Ex. P12, pp. 7-8.) Although Dr. Natanzi does not really explain this theory, his flow chart documenting the pathology of SIRVA asserts that inflammation of the rotator cuff and tendons otherwise implicated in SIRVA may also possibly aggravate calcific tendonitis. (*Id.* at 7.) Dr. Abrams disagrees with this assertion, positing that calcific tendonitis indicates a different etiology than SIRVA that is sufficient to explain acute shoulder pain. (Ex. A, p. 6.)

As Dr. Natanzi and Dr. Abrams both explain, calcific tendonitis is a condition in which calcium deposits develop in the tendons of the rotator cuff. (Ex. P12, p. 6; Ex. A, p. 6.) Eventually, the calcium deposits are resorpted[13] and the tissues remodeled to be replaced by granular tissue. (Kim et al., *supra,* at Ex. P14, Tab t, p. 2).) Neither the mechanism by which these deposits form nor the factors associated with resorption are known. (Darrieutort-Laffite, *supra,* at Ex. A, Tab 1, p. 1.) Overuse and degenerative phenomenon are less likely to fully explain calcific tendonitis because the condition tends to be observed in younger patients and is not associated with manual work. (*Id.* at 2.) Calcific tendonitis occurs gradually and over the course of three different stages, pre-calcific, calcific, and post-calcific. (Kim et al., *supra,* at Ex. P14, Tab t, p. 2.) The calcific stage itself has three phases – formative, resting, and resorptive. (*Id*.)

Dr. Natanzi does not actually explain *how* vaccination would cause calcific tendinitis to become symptomatic; however, the literature filed in this case necessarily establishes the resportive phase of the calcific stage as operative to Dr. Natanzi's theory. Whereas the formative phase is usually not painful, acute pain arises in the resorptive phase of the calcific stage and can appear suddenly. (Kim et al., *supra,* at Ex. P14, Tab t, p. 2.) This is the point at which an acute, local inflammatory process subjects the calcium deposits to phagocytosis by macrophages. (*Id*.; Darrieutort-Laffite et al., *supra,* at Ex. A, Tab 1, pp. 3-5; *see* Speed & Hazleman, *supra,* at Ex. A, Tab 3, p.

[13] "Resorption" is "the loss of substance through physiologic or pathologic means." *Resorption,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=43427&searchterm=resorption (last visited Aug. 12, 2024).

3).) Importantly, however, as Dr. Abrams explains it, this typically involves non-traumatic inflammation, and it is the process whereby calcium crystals are diffused out into the subacromial bursa that leads the calcific tendinitis itself to in turn result in painful bursitis (Ex. A, p. 6) – not the other way around as Dr. Natanzi seems to suggest.

Petitioner has filed a single case report wherein a patient experienced new onset of shoulder pain and reduced range of motion about three hours of a Covid-19 vaccination. (Klabklay et al., *supra,* at Ex. P14, Tab u.) The patient was diagnosed with calcific tendinitis and, citing *inter alia* Atanasoff, et al., the clinicians further concluded the calcific tendinitis was activated by the vaccination in the manner of a SIRVA. (*Id.* at 2 (citing Atanasoff et al., *supra,* at Ex. P14, Tab b).) Based on the overall clinical presentation, they explained their conclusion as follows:

> Not all patients with calcific tendinitis have the clinical symptom of shoulder pain, and incidences of asymptomatic calcific tendinitis have been reported from 2.7% to 20%. In our case, the injection technique was found to be correct, so other causes were considered, and following ultrasonography we found a linear calcification near the footprint of the subscapularis tendon, which immediately led to the probable diagnosis of the COVID-19 vaccination [having] precipitated the patients formerly asymptomatic calcific tendinitis to symptomatic calcific tendinitis.

(*Id*.)

As a threshold matter, the rationale stated by the case report authors reflects *post hoc ero propter hoc* reasoning. (*See* Klabklay et al., *supra,* at Ex. P14, Tab u, p. 2.) Additionally, Dr. Abrams contends this case report is of no value, because the patient experienced calcific tendinitis of the subscapular tendon whereas SIRVA is generally proximate to the supraspinatus and infraspinatus tendons. (Ex. A, p. 6.) Regardless of whether Dr. Abrams's opinion would be sufficient to rule out subscapular involvement in SIRVA, Dr. Abrams is persuasive in discounting the value of this particular case report for this reason.

The literature Dr. Abrams has submitted explains that, while the infraspinatus, supraspinatus, and subscapularis tendons may all be affected by calcific tendinitis, the subscapularis, consistent with the presentation in the above-discussed case report, is more likely to present as an acute event. "Deposits in the subscapularis tendon often remain quiescent until, or unless, an acute attack supervenes." (Harrison, *supra,* at Ex. A, Tab 2, p. 5.) These "acute attacks" are not in themselves inflammatory but are mediated by the contact between the calcium deposit and the bursal floor, which can result from "minute traumatic factors" such as minor injury or strain. (*Id*. at 4-5.) This is in contrast to calcific tendinitis of the infraspinatus and supraspinatus which tend to produce a constant aching sensation. (*Id.* at 5.) It is postulated that the presence of the

calcium deposits produces the inflammation as a "foreign body reaction to tissue irritation." (*Id.* at 3-4.)

> Probably most quiescent lesions eventually develop symptoms in some degree since the symptoms are nothing more than a subjective manifestation of nature's attempt to eradicate the lesion. It has been apparent that so long as the deposit remains buried in tendon it tends to remain quiescence, but that sooner, or later, it gradually or suddenly penetrates the overlying tendon fibers to come into contact with the floor of the subdeltoid bursa, following which an inflammatory reaction immediately is mobilized with ensuing symptoms.

(*Id*. at 4.)

The literature filed by petitioner likewise confirms that, while calcific tendinitis can be chronic or subacute (arising over three or more weeks), some cases manifest in less than two weeks and are therefore considered acute. (Kim et al., *supra,* at Ex. P14, Tab t, p. 2.) Further to this, studies have shown experimentally that the crystals implicated in the pathogenesis of painful calcific tendinitis have produced inflammation of the synovial membrane within 6 hours, with the inflammatory response peaking at 24 hours and decreasing by 48 hours. (Darrieutort-Laffite et al., *supra,* at Ex. A, Tab 1, p. 4.) While this would tend to confirm that symptoms of calcific tendinitis can arise very abruptly, it suggests that at least some period of latency is required. Thus, with regard to the Klabklay, et al, case report, this casts doubt on the idea that the Covid-19 vaccination occurring three hours prior to onset is the best explanation for the onset of the patient's painful calcific tendinitis. (Klabklay et al., *supra,* at Ex. P14, Tab u, p. 1.)

Considering all of this – the relationship between subscapular involvement and acute onset, the fact that calcium crystals produce inflammation over at least six hours, and the *post hoc ergo propter hoc* reasoning – I am not persuaded that the Klabklay, et al., case report establishes the patient's vaccination as any necessary component of his presentation. In any event, isolated case reports are not strong evidence even though they are not entirely without evidentiary value. *E.g., Caves v. Sec'y of Health & Human Servs.,* No. 07-443V, 2010 WL 5557542, at *14 (Fed. Cl. Spec. Mstr. Nov. 29, 2010), *mot. for review denied,* 100 Fed. Cl. 119 (2011), *aff'd,* 463 F. App'x 932 (Fed. Cir. 2012). Standing alone, a single case report does not support petitioner's burden of proof. Apart from this unpersuasive case report and Dr. Natanzi's *ipse dixit*, nothing else on this record purports to marry the mechanism of injury postulated for SIRVA with the pathophysiology of calcific tendinitis.

Considering all of this and the record as a whole, petitioner has not substantiated that a vaccination can cause or aggravate calcific tendinitis. Moreover, petitioner is incorrect to assert that "it is medically impossible for petitioner's shoulder pain to occur within 48 hours of the flu vaccine but be caused by a spontaneous and once-asymptomatic calcific tendinitis." (ECF No. 49, p. 31.) Rather, this record reflects that

the pathophysiology of calcific tendinitis is a complete explanation for acute shoulder pain. As the literature in this case explains, while it is a chronic condition overall, it typically culminates in an acute painful presentation that is itself an inflammatory process. This culminating process is an expected part of the course of the condition, does not require a separate inflammatory trigger to become symptomatic, and can appear suddenly. Thus, not only is petitioner's theory inadequately supported, but calcific tendinitis can actually be incompatible with SIRVA or a SIRVA-like injury.

Accordingly, petitioner has demonstrated under *Althen* prong one that vaccines can cause *some* shoulder pathologies to be activated in the manner of a SIRVA but has not met her burden of proof with respect to demonstrating that vaccination can cause asymptomatic calcific tendinitis in particular to become symptomatic.

c. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326-27; *Grant*, 956 F.2d at 1147-48. Medical records are generally viewed as particularly trustworthy evidence. *Cucuras ex rel. Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master. *See* § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. 706, 745 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.") A petitioner may support a cause-in-fact claim through either medical records or expert medical opinion. § 300aa-13(a). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.,* 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.,* 940 F.2d 1518, 1528 (1991)).

Given my resolution of *Althen* prong one, the question of whether petitioner's calcific tendinitis is merely an incidental finding is dispositive. In her motion, petitioner presents calcific tendinitis as an alternative cause, suggesting that respondent bears the burden of proof on this point. (ECF No. 49, pp. 29-31.) However, this is not persuasive. Although petitioners do not bear a burden of eliminating other causes of injury, evidence of other possible sources of injury can be relevant to determining whether a prima facie showing has been made as to vaccine causation. *Winkler*, 88 F.4th at 963 (quoting *Stone ex rel. Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012).) This is consistent with prior shoulder injury cases that have examined calcific tendinitis as a source of shoulder pain under the framework of *Althen* prong two. *Compare Bulman v. Sec'y of Health & Human Servs*., No. 19-1217V, 2023 WL 5844348 (Fed Cl. Spec. Mstr. Aug. 16, 2023) (finding calcific tendinitis defeated shoulder injury claim under *Althen* prong two) *and Peka v. Sec'y of Health & Human Servs*., No. 20-1099V, 2024 WL 1406421 (Fed. Cl. Spec. Mstr. Mar. 7, 2024) (finding petitioner entitled

to compensation for vaccine-caused shoulder injury where calcific tendinitis was an incidental finding).

As Atanasoff, et al., explained "there is no specific diagnostic test for shoulder dysfunction due to vaccine needle over-penetration." (Atanasoff et al., *supra,* at Ex. P14, Tab b, p. 4.) Thus, SIRVA and SIRVA-like injuries are identified by clinical presentation. (*Id*.) Effectively, SIRVA is an umbrella term for a phenomenon whereby various shoulder pathologies come to medical attention in close proximity to vaccination and vaccine causation is ascribed where no other explanation is available. Yet, for the reasons discussed above, calcific tendinitis is a condition that can otherwise explain the acute onset of shoulder pain. This is precisely why Dr. Natazi himself stressed in his supplemental report the importance of "context" in assessing petitioner's condition. (Ex. P15, p. 1.) In that regard, although petitioner asserts that respondent should bear a burden of proof in establishing calcific tendinitis as the cause of petitioner's shoulder pain, she nonetheless acknowledges that Dr. Natanzi's causation opinion is specifically premised on his assumption that petitioner's calcific tendinitis is only an incidental finding. (ECF No. 49, p. 27.) On this record, I am not persuaded by Dr. Natanzi's assessment of petitioner's calcific tendinitis as merely incidental for several reasons.

Three treating physicians – a primary care provider, a physiatrist, and an orthopedist, all consistently diagnosed petitioner's shoulder pain as calcific tendinitis. (Ex. P5, p. 29; Ex. P11, p. 8; Ex. P7, p. 24.) "[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano,* 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280).) Especially to the extent that Dr. Natanzi stresses "context" as the key to distinguishing a possible SIRVA from calcific tendinitis (Ex. P15, p. 1), these treating physicians were all aware of petitioner's report of an abrupt post-vaccination onset. (Ex. P5, p. 26; Ex. P11, p. 7; Ex. P7, p. 24.) Moreover, the physiatrist specifically contrasted the diagnosed calcific tendinitis against a possible SIRVA, determining that her presentation was more consistent with calcific tendinitis. (Ex. P7, p. 24.) Even as the orthopedist felt that petitioner's pain was unusually chronic for a calcific tendinitis, he maintained the diagnosis and his anticipated surgical plan was for a resection of the calcium deposit. (Ex. P11, p. 8.) This is incompatible with any suspicion that the deposit was an incidental finding.

Dr. Natanzi is also not persuasive in contending that petitioner's response to steroid injection meaningfully distinguishes the nature of petitioner's shoulder pain. (Ex. P12, p. 6.) Although he may be correct to suggest that response to steroid treatment could be indicative of an inflammatory response such as SIRVA, calcific tendinitis in the resorptive phase is also an inflammatory condition. (Harrison, *supra,* at Ex. A, Tab 2, pp. 3-4.) The literature filed in this case reflects that steroid injections are among the treatments known to provide at least temporary pain relief from calcific tendinitis during the resorptive phase, though some argue anti-inflammatory treatment impedes the healing aspect of the resportive process. (Speed & Hazleman, *supra,* at Ex. A, Tab 3, p. 3.) Thus, given the conditions at issue, petitioner's response to steroid injection does not imply a SIRVA-like process.

Although I do not find Dr. Abrams persuasive in contending that petitioner had full range of motion, Dr. Natanzi ultimately does not present this as a dispositive issue. In his supplemental report, Dr. Natanzi explains that "[i]t is important to acknowledge that calcific tendinopathy to the supraspinatus or infraspinatus tendon and a SIRVA can both demonstrate very similar physical exams with pain, range of motion deficits, and impingement signs." (Ex. P15, p. 1.) And, although Dr. Natanzi purports to rely on "context" to distinguish the two conditions, petitioner is unpersuasive for the reasons discussed under *Althen* prong one above, in contending that the abrupt post-vaccination onset in this case is impossible from a spontaneous calcific tendinitis. As Dr. Abrams opines, calcific tendonitis is known to be capable of an acute onset. (Ex. A, p. 6.) Moreover, as explained above, calcific tendonitis was the diagnostic impression of the treating physicians.

Finally, I note that, even setting diagnosis aside, none of the treating physicians otherwise expressed any belief that petitioner's shoulder pain could have been vaccine-related. The only physician that recorded such consideration – the physiatrist – contrasted a potential SIRVA against calcific tendinitis and concluded that calcific tendinitis was more likely based on petitioner's own presentation and declined to implicate the vaccination. (Ex. P7, p. 24.)

For all these reasons, petitioner has not met her burden of proof under *Althen* prong two.

d. *Althen* prong three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. 418 F.3d at 1278. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *mot. for recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd*, 503 F. App'x. 952 (Fed. Cir. 2013); *Koehn ex rel. Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

In Trollmo, et al., all of the subjects that received injections into their joints experienced swelling and stiffness of the joint within 2-4 hours. (Trollmo et al., *supra,* at Ex. P14, Tab i, p. 3).) This is also consistent with the timing of onset within the case report submitted by Dr. Natanzi. (Klabklay et al., *supra,* at Ex. P14, Tab u, p. 1.) Additionally, studies have shown experimentally that the crystals implicated in the pathogenesis of painful calcific tendinitis have been shown to produce inflammation of the synovial membrane within 6 hours of injection, with the inflammatory response

peaking at 24 hours and decreasing by 48 hours. (Darrieutort-Laffite et al., *supra,* at Ex. A, Tab 1, p. 4.) Thus, if one were to accept under *Althen* prong one that vaccine-induced inflammation could commence the resorptive phase, there is little reason not to conclude that the process could happen in a timeframe similar to SIRVA.

Accordingly, given the Chief Special Master's ruling that onset of shoulder pain occurred within 48 hours of vaccination, had petitioner met her burden under *Althen* prong one then I would have concluded she also met her burden under *Althen* prong three.

VII. Conclusion

Balancing all of the above, and based on the record as a whole, I conclude that petitioner has not demonstrated by a preponderance of the evidence that she suffered a shoulder injury attributable to her October 4, 2018 flu vaccination. Instead, her condition was diagnosed as calcific tendinitis, which has not been shown to be vaccine caused. Although petitioner stressed her abrupt post-vaccination onset of shoulder pain, she has not demonstrated that this is incompatible with calcific tendinitis unrelated to vaccination. Accordingly, this case is dismissed.[14]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[14] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.